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10/056,136	01/24/2002	Nobuyuki Tatsumi	NGB-12930	2328

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,136	TATSUMI, NOBUYUKI	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1-24-02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The disclosure is objected to because of the following informalities: On page 2, the words in the paragraph run together. There's no spacing between words.

Appropriate correction is required.

Claim Interpretation

3. Claim 4 recites "a quartz thin film that is formed on said needle by a chemical vapor deposition method." The method by which the quartz is placed on the needle does not further limit the structure of the device. As such, an equivalent device comprising a quartz coating placed thereon by different process would meet the limitations of the claim.

Claim Rejections - 35 USC § 112

4. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 specifies what or how the device is intended to be used. Such recitation does not further limit the structure of the device.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 5, 11, and 12 rejected under 35 U.S.C. 102(b) as being anticipated by El-Hage et al. US 5,843,378.

El-Hage et al. teaches aspirating and dispensing probes are often used to transfer liquids between various vessels (plurality of vessel) and compartments in a chemical analyzer. The liquids typically include samples to be tested and reagents for testing the samples.

A preferred embodiment of the invention is illustrated in FIGS. 1-9. FIG. 1 shows a probe 10 for dispensing and aspirating liquid into and out of a vessel 14. Vessel 14 is held in a rack 16 which is mounted on a carousel. Probe 10 is attached to a probe positioning device, such as a mechanical arm 12. Arm 12 is designed to position probe 10 in an appropriate vessel for aspirating or dispensing liquid. Such mechanical arms for positioning probes are well known in the art.

FIG. 2 shows a cross sectional view of probe 10 (needle) and a portion of arm 12. Probe 10 includes an electrically insulative tube 18, an electrically conductive fluid conduit 26, and an electrically conductive rod 30. Conduit 26 and rod 30 are made of a relatively inert material so that they do not chemically react with sample and reagent liquids. The inert material is preferably stainless steel or gold-coated copper.

7. Claims 1, 2, 5, 6, 8, 9, and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith US 4,309,912.

Smith discloses an improved process and device for facilitating micro-analysis of samples under ten microliters with good accuracy-precision wherein a sample together with another liquid substance are simultaneously delivered into a receptacle in a suitably small volume, including a self-cleaning feature enabling reuse without a specific washing step or changing a disposable part; additionally, such process and device include a capability for making serial dilutions. The device used to transfer the precise volumes of liquid is a probe.

The greatest diameter and over-all length of tips 11 and 27 is such as to permit insertion into clinical specimen containers such as blood sample tubes or the like. Additionally, probes 23, 28 range in length from 3-100 millimeters, preferably 20 millimeters, as measured from the lower edge 20 or comparable member of the respective tips; said probes are desirably of corrosion resistant metallic composition such as gold, cadmium or nickel plated steel, and stainless steel.

8. Claims 1-2, 6, 8, 9, and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoskins et al. US 3,883,305.

Hoskins discloses an automatic chemical analysis apparatus having separate closed-looped conveyors for sample and reactant containers (plurality of vessels). At a fixed location, sample portions from a given sample are transferred to a serial sequence of reactant containers.

The pipette is shown in greater detail in FIG. 7 and comprises a gold-plated stainless steel tube 300 of 2 mm outside diameter provided with a bore. The outer diameter tapers to 1 mm within a brass cylindrical member 301 of 5 mm diameter and 5.5 mm length which encompasses said tube 300.

9. Claims 1-2, 6, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by King et al. US 6,132,582.

A sample handling system in a multi-channel capillary electrophoresis apparatus is disclosed. The sample handling system includes a work surface for supporting a plurality of samples located at a plurality of work surface coordinates (plurality of vessels) and a sample loading assembly comprising a plurality of loading wells. At least one of the loading wells includes a capillary fixedly positioned therein. The system further includes a programmable sample transfer device for automatically transferring a sample from a work surface coordinate to a loading well.

The material used to fabricate the pipette (needle) will depend upon the requirements of a particular application. Factors to be considered include wetability, rigidity and conductivity. Where the sample is a liquid, the wetability of the pipette should be such that sample may be introduced into the pipette in a controlled and reproducible manner. When the pipettes are passively loaded with sample using

capillary action, generally the pipette should be wetable by the sample material. It is preferable that the pipette be rigid in order to facilitate location of the inlet end of the pipette with respect to the robot arm. Finally, where an electrical measurement is used in the tip sensor, the pipette should be electrically conductive. Preferred pipette materials include but are not limited to stainless steel, platinum and gold coated materials, glass, fused silica, and plastic or plastic coated materials, e.g., stainless steel coated with a parylene.

10. Claims 1, 3, 5, 9, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Hutchens et al. US 2002/0155620.

Hutchens et al. disclose a device and method for spotting samples on a substrates such as slides (plurality of vessels). The device comprises a probe tip, or sample plate, for selective adsorption/presentation of sample for mass analysis are (1) stainless steel (or other metal) with a synthetic polymer coating (e.g., cross-linked dextran or agarose, nylon, polyethylene, polystyrene) suitable for covalent attachment of specific biomolecules or other nonbiological affinity reagents, (2) glass or ceramic, and/or (3) plastic (synthetic polymer). The chemical structures involved in the selective immobilization of affinity reagents to these probe surfaces will encompass the known variety of oxygen-dependent, carbon-dependent, sulfur-dependent, and/or nitrogen-dependent means of covalent or noncovalent immobilization. The methods and chemical reactions used in producing such surfaces derivatized with biospecific affinity reagents already are known by those skilled in the art. Two features of the invention, however, are (1) the specific size and localization of the derivatized surface with respect

to the laser beam and (2) the affinity directed presentation of specific analyte molecules (e.g., macromolecule or biopolymer) at a defined surface density or local concentration required for the efficient detection by laser desorption/ionization time-of-flight mass spectrometry. This can be accomplished by arranging the affinity adsorption "spots" (0.005 to 0.080 inch diameter) on the probe surface in a defined manner (400 to 1,000 spots could be placed on a surface about the size of a glass slide).

Hutchens et al. also discloses "All known prior art procedures which present proteins or other large biomolecules on a probe tip for laser desorption/ionization time-of-flight mass spectrometry rely on a crystalline solid mixture of the protein or other analyte molecule in a large excess of acidic matrix material deposited on the bare surface of a metallic probe tip. **(The sample probe tip typically is metallic, either stainless steel, nickel plated material or platinum)**. Immobilizing the analyte in such a matrix was thought to be necessary in order to prevent the destruction of analyte molecules by the laser beam. The laser beam strikes the mixture on the probe tip and its energy is used to vaporize a small portion of the matrix material along with some of the embedded analyte molecules. Without the matrix, the analyte molecules are easily fragmented by the laser energy, so that the mass, and identity, of the original macromolecule is very difficult to determine."

11. Claims 1-2, 6, 9, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. by US 6,365,024.

Li et al. discloses an automated electrophoretic system is disclosed. The system employs a capillary cartridge having a plurality of capillary tubes. The cartridge has a

first array of capillary ends projecting from one side of a plate. The first array of capillary ends are spaced apart in substantially the same manner as the wells of a microtitre tray of standard size (plurality of vessels). This allows one to simultaneously perform capillary electrophoresis on samples present in each of the wells of the tray.

FIG. 3A shows a needle 140 used in forming a tube assembly 160 which can then be directly inserted into a mounting plate 162, as shown in FIG. 3B. The needle 140 comprises a metallic cannula 142. In the preferred embodiment, the cannula 142 is formed from stainless steel having an inner diameter of 0.064 in. and an outer diameter of 0.072 in. The cannula 142 is provided with a bevel 144 at the end which is dipped into a well.

As is known to those skilled in the art, the voltage differential may be delivered to the first capillary ends through other means as well. For instance, instead of contacting a common plate to which the needles are connected, voltage leads may be connected directly to each needle. Alternatively, individual leads may be dipped into the liquid in each well. Another alternative is to deliver the voltage through a metallic coating, such as gold, deposited on the exterior of only the terminal portion of each capillary tube, where it contacts the liquid in the well. Also, the voltage may be delivered directly to the wells through one or more leads, as described earlier. One skilled in the art can readily formulate alternative approaches to delivering a voltage to the first capillary end.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 9 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over El-Hage et al. US 5,843,378 as applied above.

El-Hage does explicitly recite the inert coating as being on the exterior of the probe. However, El-Hage states "conduit 26 and rod 30 are made of a relatively inert material so that they do not chemically react with sample and reagent liquids." This

statement implies that that both the inner and outer surface are coated with the material for both surfaces come in contact with the sample and reagent liquids.

On the other hand, if one asserts that the tube is not coated on the exterior, it would have been obvious to one of ordinary skill in the art at the time of the invention to coat the exterior surface of the probe as well to prevent the liquids from reacting with the probe surface.

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchens et al. as applied to claims 1, 3, 5, 9, 11, and 12 above, and further in view of Smith 6,482,2362 or in the alternative Turner et al. US 6,455,316.

Hutchens et al. does not specify that the resin coating is polyetheretherketone (PEEK).

Both Smith and Turner disclose probe or liquid transfer devices comprising PEEK.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Hutchens et al. by coating it PEEK material in order to prevent the base material of the probe from reacting with the samples.

17. Claims 4 and 10 rejected under 35 U.S.C. 103(a) as being unpatentable over El-Hage et al. as applied to claim 1 above, and further in view of Harris Sr. US 4,404,862.

Hage et al. does not disclose employing quartz as a coating.

Harris Sr. discloses a needle which may be attached to a syringe or dispensing device for transferring fluids.

In many applications however, the needles are not constructed of mechanically strong materials, and in fact the materials employed are often structurally weak. The walls of the needles are sometimes thin, and brittle. It is thus necessary on occasion to construct needles of materials which are chemically inert, or non-reactive with the fluids to be sampled, e.g. strong acids, or bases. The walls forming such needles are often necessarily thin, fragile and incapable of withstanding strongly applied forces without fracturing or breaking. For example, it is desirable to construct very small diameter needles of fused silica, glass, or quartz. While needles constructed with such materials are highly non-reactive chemically with many fluids, they are structurally weak and incapable of withstanding highly compressive mechanical forces without fracturing, or breaking.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of El-Hage et al. by substituting the gold coating with quartz to provide a non-reactive protective layer to the probe. Quartz is also known to be more readily available and more economical than gold.

Conclusion

18. No claims allowed.

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sklar, Larry A et al.; Wiktor, Peter; Houck, Raymond K. et al.; Cole, Richard B. et al.; Houck, Raymond K. et al.; Gross, Joseph et al.; Hagiwara, Teruhiko; Karkantis, Peter N. et al.; Karkantis, Peter N. et al.; Liston, Max D. et al.;

Andresen, Brian D. et al.; Beaudoin, Paul et al.; Smith, Kendall O.; and Oppegaard, Asbjorn disclose fluid transfer devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg

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